10-031,757
PTO/[illegible] Rec'd 17 JAN 2002

PACEMAKER

Technical Field

The present invention relates to a pacemaker operable in a tracking and a non-tracking mode and having an automatic mode switching function for switching the pacemaker into a non-tracking mode of operation in response to the detection of an atrial tachycardia, said pacemaker including atrial detecting means for detecting atrial events, ventricular detecting means for detecting ventricular events, an atrial interval determining means for determining the interval between consecutive atrial events, a comparison means for comparing said interval with a predetermined atrial tachycardia limit value for recording a tachy indication if said interval is less than said atrial tachycardia limit value, and a mode switching means for switching the mode of operation to said non-tracking mode when the number of recorded tachy indications reaches a predetermined tachy count limit.

Background

Patients with paroxysmal atrial tachycardias who require e.g. DDD pacing run the risk to enter into a situation of inappropriate rapid pacing due to tracking of the atrial rhythm. It has been observed that a non-physiologic high ventricular stimulation rate in a tracking mode of operation is the primary source of the suffering of the patient and not the atrial tachycardia in itself. As a rule, more than 50% of patients, which have had periods of atrial tachycardia before the implantation of a pacemaker, will have it again, and more than 30% of pacemaker patients which have not had any suspected atrial tachycardia will get at least one episode of tachycardia during a five year period after implantation. If these patients were paced with a pre-set rate, possibly modulated by a rate-adaptive sensor, they would not have AV synchrony during periods of sinus rhythm and therefore be compromised. Several solutions comprising mode switching have

therefore been proposed to avoid inappropriate tracking of atrial arrhythmias and to provide tracking of the sinus mode at all other times. Usually such a mode switch of the pacemaker changes the mode of response to atrial sensed events from a tracking to a non-tracking mode. When the atrial rhythm exceeds a predetermined detection rate for a set number of intervals the ventricle will consequently be paced at a predetermined rate and when sinus rhythm resumes, the pacemaker is switched back to an atrial tracking mode.

Thus in e.g. US-A-5,085,215 a metabolic demand driven rate-responsive pacemaker is described, which is switched into a VVI mode, when a maximum atrial tracking rate is reached. In the VVI mode ventricular pacing pulses are generated at a rate which is a function of a metabolic indicator rate and independent of atrial heartbeat sensing.

US-A-5,514,164 discloses an implantable pacemaker normally operating in a DDD mode and reverting to a modified DDI mode in response to the sensing of atrial depolarisation early in the pacing cycle. The DDI mode operates in the same way as the DDD mode except that the atrial signals are not tracked. Hence, detection of P-waves in the DDI mode result in inhibition of atrial output with normal ventricular timing. The DDI mode continues only to the end of the pacing cycle. During the next pacing cycle the DDI mode is initiated again only if a P-wave is again sensed early in the pacing cycle, otherwise DDD pacing continues.

There is a need for improvement of automatic mode switch algorithms known today.

Some prior art algorithms may be considered slow because of too long a period of confirmation before the mode switch occurs and some systems switch mode incorrectly caused by improper detector design resulting in false indications in conjunction with too short a confirmation period. Some automatic mode switch systems do not have a reliable signal

sensing, which may also result in non-detection of some cardiac events. Further, unnecessarily long refractory periods of prior art systems may give blindness to atrial tachycardia and the time from tachycardia starts until mode switch is very unpredictable and depending on the tachycardia rate or programmed tachycardia limit.

There does not exist any automatic mode switch design today, which is suitable for all types of patients. A few patients prefer a longer time for the mode switching, typical several seconds, if false mode switchings can be avoided in this way. However, most of the patients want to avoid any unnecessarily high stimulation rates, even for a few seconds.

A correct signal detection is the first and most important factor for a satisfactory mode switch function. Several types of pacemakers are provided with only one atrial signal detector. When the sensitivity of this detector is adjusted appropriately for detection of normal P-waves, some types of atrial tachycardias will be detected only intermittently. The mode switching then has to be based on ”guessings”. Further, during pacemaker implantation and the accompanying follow-up atrial tachycardia signals are most often not obtainable. It is therefore an obvious risk that the physician will choose a sensitive setting, which is too high or too low for atrial tachycardia detection. Often a very high sensitivity is chosen, which together with unsuitable filter designs may result in the detection of R-wave farfields and also interferences, which may influence the normal pacing rate and even give rise to false mode switches.

This detector sensitivity dilemma is one reason for a problematic mode switch function of several existing products.

Thus, to distinguish an atrial tachycardia from an interference or some premature heart signals merely by measurement of atrial intervals and counting of the number of such

intervals might not be sufficient. As a matter of fact several factors have to be considered.

If farfield R-waves are sensed by the atrial detector the pulse generator timers of the pacemaker will be restarted with restart of refractory periods as well. Ventricular stimulations with accompanying blanking periods are also synchronized to the sensed atrial signal, the stimulation rate being of course limited by the maximum tracking rate. The blanking intervals, which may cover atrial events, are consequently repeated more frequently. All these intervals resulting from a mixture of sensed and stimulated events must be considered when designing an automatic mode switch system and not only the free atrial-atrial signals.

If spontaneous ventricular beats are omitted, three different situations of mixed sensed and stimulated cardiac occurrences are possible during an atrial tachycardia in DDD mode of operation of a pacemaker. These situations are illustrated by symbolic ECG's shown in figure 1 a), b) and c).

AF denotes an atrial signal, which can be a P-wave, flutter or fibrillation sensed on the atrial electrode. V denotes a ventricular stimulation pulse, and ? denotes the associated blind atrial blanking period, during which an atrial signal may have occurred.

The situation illustrated at a) in figure 1 is characterized by one atrial signal AF intervening between two ventricular stimulations V. An atrial signal can be hidden during the atrial blanking ?. Since this situation can be stable during an atrial flutter, it can be hard to distinguish between atrial flutter and a normal situation with a high sinus rate without any hidden signals. Even if not all the atrial signals are hidden during an unstable tachycardia, a sufficient number of atrial signals can disappear such that a pacemaker, the control of which is based on long/short atrial intervals, can be wrongly operated. The only effective

solution to this problem consists in changing the stimulation interval, such that when the time of ventricular stimulation is altered, the atrial blanking interval will not be positioned on half the atrial-atrial signal interval.

The situation according to b) in figure 1 with two atrial signals AF between two consecutive ventricular stimulations V will make detection possible for all situations provided that the used pulse generator design does not involve unnecessary refractory periods. The algorithms used for controlling the pacemaker can be more or less effective in situations of coverage of some of the atrial signals by the post ventricular atrial blanking periods ?, because there will be a measured long atrial interval which can counteract the tachycardia determination.

At c) in figure 1 a situation is shown with three atrial signals AF appearing between each two consecutive ventricular stimulations V. In this case correct AF detection will be possible, provided that the pulse generator design does not involve unnecessary refractory periods and provided that there is no interference protection, which may be erroneously operated by the detected high rate. For this situation, with a very high atrial rate, there is a higher probability for coverage of some of the atrial signals by the post ventricular atrial blanking periods ?. If long atrial counting intervals are used in the algorithms for controlling the pacemaker, a slowing down can occur before the mode switch.

Only at extremely high atrial rates and extreme parameter settings four atrial signals AF may occur in one V-V interval. This case is principally similar to the situation shown at c).

Another important factor, which may give rise to problems, is the consideration time from a detection of a short AF-AF interval until a mode switch takes place. Depending on the signal detector design the needed confirmation time will be

shorter or longer for one and the same patient depending on the sequence of heart signals in conjunction with other pacemaker timings, such as refractory periods and stimulation intervals. This means that the mode switch confirmation time very often cannot be predicted.

The purpose of the present invention is to provide a pacemaker operable in a tracking or a non-tracking mode of operation having an improved mode switching function for switching the pacemaker into the non-tracking mode of operation in response to the detection of an atrial tachycardia.

Disclosure of the Invention

This purpose is obtained with a pacemaker as defined in the opening paragraph of the description having the characterizing features of claim 1.

Thus, in the pacemaker according to the present invention, not only atrial intervals but also other cardiac event intervals are analysed during a predetermined number of stimulation intervals to obtain a safe indication of whether a tachycardia exists or not.

If the atrial-atrial signal interval is shorter than the tachycardia limit value and no other cardiac event interval is longer than this limit in the considered V-V interval, this is used as a tachy indication. If at least one measured interval between any combination of sensed cardiac events or stimulations during a V-V interval is longer than the tachycardia limit value this is considered as a non-tachy indication. If there is no atrial indication of tachy nor any indication of non-tachy during an V-V interval, then the mode change counter is not altered.

In the pacemaker according to the invention the necessary logic of the mode switching means is reduced compared to prior art designs. Due to its simplicity it will be more safe and easier to validate. Further, the number of programmable

parameters will be few, which consequently reduces the work of the physician and reduces the risks of mistakes. The time from the start of a tachycardia to the mode switch and back in the opposite direction is predictable and independent of the tachycardia rate, and can be selected in accordance with the patient's preferences.

According to an advantageous embodiment of the pacemaker according to the invention the atrial detecting means comprise a P-wave detector for detecting ordinary P-waves and an atrial tachycardia detector of higher sensitivity for monitoring atrial tachycardia signals. Thus synchronisation and stimulation are controlled by a detector having sensitivity suitable for detection of normal P-waves, while the monitoring for detecting an atrial tachycardia is performed by a more sensitive detector. In this way the above mentioned detector sensitivity dilemma is remedied.

According to other advantageous embodiments of the pacemaker according to the invention the mode switching means comprises an up/down counter which is adapted to be counted up by one for each tachy indication and counted down by one for each non-tachy indication. When the number of ventricular stimulation intervals with indicated tachy has reached a programmed limit, a mode switch to the non-tracking mode occurs. The programmed limit can preferably be in the range of 1-8 intervals. In this way a higher security is obtained for switching modes only in response to the detection of a true tachycardia. If, on the other hand, longer intervals are detected in the non-tracking mode of operation, a consideration process starts for eventually switching back to the tracking mode. If indications of non-tachycardia are obtained during the consideration process, the counter is counted down and when the counter reaches a predetermined limit the mode switching means is triggered to change the mode of operation back to the tracking mode. Thus, in said non-tracking mode of the pacemaker, said mode switching means is adapted to switch mode of operation back to the tracking

mode when its tachy indication counter is counted down by a predetermined number from said predetermined tachy count limit.

According to yet another advantageous embodiment of the pacemaker according to the invention a means is provided for changing the AV interval in order to uncover possible atrial events covered by the ventricular blanking period. In this way a more reliable detection of the atrial tachycardia is achieved and consequently a more reliable mode switch function.

The stimulation rate can be P-wave controlled, atrial tachycardia signal controlled during the transitional phase of considerating a mode switch or equal to a base rate in case of failing heart activity. According to an advantageous embodiment of the pacemaker according to the invention said base rate is sensor controlled.

Brief Description of the Drawings

To explain the invention more in detail an embodiment of the pacemaker according to the invention, chosen as an example, will now be described with reference to figures 2-11 on the drawings, on which

Figure 1 shows symbolic ECG's for three different situations of mixed cardiac events,
figure 2 shows an overview of a pacemaker system according to the invention,
figure 3 shows the electronics of the pacemaker according to the invention in block form,
figure 4 illustrates the Mode Switch Electronics of the pacemaker according to the invention,
figure 5 shows a Generalised Counter Block for counting clock signals for time measurements in the pacemaker according to the invention,
figure 6 illustrates more in detail the Generalised Counter Block shown in figure 5,

figure 7 shows the counter in figure 6 more in detail,
figure 8 shows the Atrial Interval Counter in the form of a generalised counter block,
figure 9 shows a Cardiac Event Interval Counter in the form of a generalised counter block,
figure 10 shows more in detail the Automatic Mode Switch (AMS) Check Block of figure 4, and
figure 11 shows more in detail the counter of the AMS Check Block shown in figure 10.

Description of a Preferred Embodiment

Figure 2 shows and overview of the whole system of the pacemaker according to the invention including a pulse generator 2 with DDD functions and mode switch electronics for changing the mode of operation from the tracking DDD mode to a non-tracking mode of operation, like a DDI mode, in response to the detection of an atrial tachycardia, and back again to the tracking DDD mode when the tachycardia no longer is detected. The pacemaker 2 is connected through atrial and ventricular leads 4, 6 including associated electrodes 8, 10 to the atrium 12 and the ventricle 14 respectively of a patient's heart 16.

Figure 3 shows in the form of a block diagram the electronics of the pacemaker 2 in figure 2. Block 18 is a service unit comprising electronics for test, control and communication, like means for telemetry, diagnostics, storage of measured data, power supply control etc. These means are not of primary importance for the invention and are well known to the man skilled in the art and will consequently not be described in greater detail.

The pulse generator 20 is a timing unit, comprising DDD and DDI timing functions including electronics for control of time intervals and output of the pacemaker.

Block 22 represents mode switch electronics including means for signal monitoring and means for controlling the modes of operation. The different parts of this mode switch electronics 22 will be described more in detail below. Blocks 24 and 26, intended to be connected to the atrial lead and the ventricular lead respectively, comprise electronics for atrial stimulation output and ventricular stimulation output respectively, as well as signal detections. Thus these blocks 24, 26 include heart signal amplifiers and detectors, stimulation output stages, protection components and de-coupling capacitors.

Figure 4 shows the Mode Switch Electronics of block 22 in figure 3 in greater detail. This mode switch electronics 22 comprises an Atrial Tachycardia Counter 28 and a Cardiac Event Interval Counter 30 in the form of two generalised counter blocks for checking intervals as will be described more in detail in the following.

An Automatic Mode Switch (AMS) Check Block 32 comprises electronics which are active during a check or consideration phase to determine if a switch of the mode of operation of the pacemaker shall occur or not. The block 32 includes a counter, described in greater detail with reference to figures 10 and 11 in the following, which is arranged to count up or down depending on the controlling in-signals.

A start signal is created by the logics formed of the network of logic gates 27, 29, 31, 33 and 35 shown in the figure. Thus in the DDD mode, when an atrial interval shorter than the tachycardia limit value is detected, a start signal will be generated. In a DDI mode, when one interval between any of two cardiac events, as measured by the Cardiac Event Interval Counter 30, is longer than the tachy limit value a start signal will also be generated.

An index register 34 is provided for storing the last decided mode during a new consideration phase, in which the automatic mode switch check block 32 is active.

Figure 5 shows a generalised counter block used as Atrial Tachycardia Counter 28 and additional cardiac event interval counter 30 in figure 4. The block 36 includes logic for control, counting of clock signals, and memorising indications.

The function of the counter block 36 is as follows:

After receiving a start signal on the Start Event line 38, every clock pulse 40 is counted until the first of two possible events occurs. These events are the number of clock pulses 40 passes a specific pre-set value, set data 42, or a signal appears on the stop event line 44. Which of these two events that happens first is indicated on the line c/o control 46. After a Start Event 38, during counting of the block 36, it is indicated on a Control During Counting line 48 that the counter block 36 is active.

The counter block 36 used as an Atrial Tachy Counter 28, see figure 4, is a time counter for determining the time between the detection of two consecutive atrial signals AF. The counter 28 starts and stops on detection of atrial signals or as a result of time out. Other cardiac events do not influence this counter 28. At an atrial signal AF detection the counter 28 is loaded with the predetermined tachy count limit ATI and the real time clock, 40 in figure 5, will count down the counter 28. A new AF detection before the counter has reached zero results in a tachy indication. The occurrence of a time out, i.e. the counter 28 reaches zero, or an intervening ventricular stimulation V or ventricular signal detection R-wave results in a dismissed indication.

The counter block 36 in figure 5, used as Cardiac Event Interval Counter 30 in figure 4, is started and stopped on

every cardiac event according to the following decision table.

Denominations for the decision table

A	Atrial stimulation
V	Ventricular stimulation
P	Atrial signal detection / P-wave detector
AF	Atrial signal detection
R	Ventricular signal detection / R-wave
VB	End of ventricular blanking period
ATI	Atrial Tachycardia Limit
UCP	UnCovering Process necessary to find eventually atrial signals during ventricular blanking

Decision Table of Tachycardia

Interval	Limit check	Decision
AF-AF*	< ATI	tachy
AF-AF	> ATI	non-tachy
AF-V	< ATI	dismissed
AF-V	> ATI	non-tachy
AF-R	< ATI	dismissed
AF-R	> ATI	non-tachy
AF-A	< ATI	dismissed
AF-A	> ATI	non-tachy
VB-AF	< ATI	dismissed, UCP
VB-AF	> ATI	non-tachy
VB-R	< ATI	dismissed
VB-R	> ATI	non-tachy
VB-A	only > ATI	non-tachy

Decision Table for the Mode Change Counter (MCC)

All indications are used during the period from one ventricular stimulation to the next ventricular stimulation.

Indications	Counts
Tachy Indication & Dismissed Indications	MCC + 1
Non-tachy Indication & Dismissed Indications	MCC - 1
Only Dismissed Indications	MCC no change
Tachy Indication, then Non-Tachy Indication (and eventually Dismissed Indications)	MCC -1
Non-Tachy Indication, then Tachy Indication (and eventually Dismissed Indications)	MCC +1

At the start the counter 30 is loaded with the predetermined Atrial Tachycardia Limit ATI and the real time clock 40, see figures 4 and 5, will count down the counter 30. Any stop of the counter 30 before it reaches zero will result in a dismissed indication and a time out of the counter 30 in a non-tachy indication as appears from the decision table above.

The Atrial Tachycardia Limit ATI, which is the interval limit value used in the pacemaker electronics, is programmable. The selected corresponding rate limit can thus be varied, preferably in steps of 10 beats per minute within the range 150-250 beats per minute.

Figure 6 shows the structure of the generalised counter block 36 shown in figure 5.

The counter block 36 controls other logic parts in the pacemaker through the two control lines c/o control 46, and Control During Counting 48. On the Control During Counting line 48 it is indicated that the counter is active, as mentioned before. On the c/o control line 46 it is indicated whether the counter has reached the same number of clock pulses 40 as the set binary value on line 42, cf. figure 5, or if the counting has been stopped by a stop event, 44 in

figure 5, before counting out. These two possible occurrences result in opposite status on the c/o control 46.

The counter block 36 comprises a register 50 in which set data values are stored. These set data can be supplied from an external device through telemetry or be produced internally in the pacemaker, cf. figure 3, and are normally kept constant. However, when new set data shall be stored these are supplied on data lines 52 and this supply is controlled by the load new data line 54.

The operation of the block shown in figure 6 is as follows. A Start Event control signal 56 is supplied through an AND-gate 58 having one of its inputs inverted to a unit 60 for reshaping the signal to a pulse suitable for processing in the counter block 62. A flip-flop Counting Active Index 64 is set to ON status by the reshaped start pulse delivered by the pulse shaping unit 60. This status information appears on the Control During Counting line 48. The reshaped start pulse delivered by the pulse shaping unit 60 also controls loading of binary data stored in the set data register 50 into the counter box 62.

When clock pulses are supplied through the AND-gate 66 to the counter 62 and the counting is active, the binary value in the counter 62 is counted down. When the count value zero is reached all binary bits in the counter 62 are equal to zero. On the next clock pulse all bits in the counter 62 will be changed to "one". There is one bit more in the counter 62 than the most significant bit in the value and when this extra bit changes from "zero" to "one", a Count-Out is indicated on the c/o control line 46. Said most significant bit is always loaded from the set data register 50 as a "zero". At the Count-Out status the flip-flop Counting Active Index 64 is set to OFF status.

The gates shown in the block diagram in figure 6 control safe processing of the counter 62. Thus the AND-gate 66 which is

connected to the clock input, secures that the counter 62 only counts down when the counter block is in its active stage.

The Start Event line 56 is connected to the pulse shaping unit 60 through an AND-gate 58 with one of its inputs inverted to protect loading of set data again after the counter has been active.

A similar AND-gate 68 with one of its inputs inverted is connected to a Count-Out Index 70 to prevent a Stop Event on line 72 through the OR-gate 74 and the pulse shaping unit 76 from changing this index after a Count-Out has occurred. The OR-gate 74 stops and resets the Counting Active Index 64 either as a result of a Stop Event on line 72 or a Count-Out event.

Figure 7 shows the counter box 62 in figure 6 in more detail. The counter 62 comprises an enough number of binary stages 78, 80 ... 82. In addition thereto there is an extra binary stage 84. Each binary stage 78, 80, 82, 84 can be loaded with one bit, "zero" or "one", from the set data register 50 in figure 6. This supply of set data is gated to occur when the load new data line 54, see figure 6, gets a pulse. The extra binary stage 84 will be loaded with the value "zero". When the counter 62 in figure 5 has counted down to the value "zero" on all stages 78, 80, ... 82, 84, all stages 78, 80, ... 82, 84 will switch to "one" in response to the next pulse. The signal from the last stage 84 is controlling the Count-Out indication and the deactivation of the counting.

Figure 8 shows the Atrial Tachy Counter (ATC) 28 of the Mode Switch Electronics shown in figure 4 in the form of a generalised counter block. This counter measures the time between two consecutive atrial events and compares this time with a predetermined Atrial Tachy Limit 86. An event can be any detection by the atrial P-wave detector or atrial tachycardia signal detector in the case when two separate

atrial detectors are used. If there are other cardiac events during the counting procedure, e.g. a ventricular stimulation, these events shall not influence this counter.

The set value of the counter 28 is the programmed Atrial Tachy Limit 86 for an atrial tachycardia.

In the example shown in figure 8 the output signal c/o on line 88 indicates that the last measured interval was not a tachy interval because there has been a Count-Out. This means that the signal on the c/o-line 88 is reversed. This is one essential element in the mode switch determination.

Figure 9 shows the Cardiac Event Interval Counter 30 in figure 3 in the form of a corresponding generalised counting block. With this counter 30 the time between the two latest cardiac events is measured and compared with the Atrial Tachy Limit.

Starting events 90 can be end of post ventricular atrial blanking (PVAB), which is a protection period in the detectors after a ventricular stimulation, and the end of post atrial-atrial blanking (PAAB), which is a protection period in the detectors after an atrial stimulation, an atrial tachycardia signal detection, P-wave detection or R-wave detection. R-wave detection can only be used if the so-called Combipolar mode of sensing is used, see below.

In a corresponding way stop events 92 can be a ventricular stimulation V-stimulation, an atrial stimulation, an atrial tachycardia signal detection, a P-wave detection or a R-wave detection, the last mentioned detection being possible only in case of Combipolar mode of sensing.

The set value 94 is also in this case the programmed Atrial Tachy Limit for an atrial tachycardia. In the example illustrated in the figure an output c/o-signal on output 96 indicates that the measured interval was not a tachy interval, since there was a Count-Out. The non-tachy indication on

the output 96 is one essential element in the mode switch determination.

Figure 10 shows in the form of a block diagram the Automatic Mode Switch (AMS) Check Block 32 in figure 4. Most elements of the AMS Check Block are equal to those of the Generalised Counter Block 36, illustrated in figure 6. It is added the functions of counting up the counter 98 and comparison of the counter value with the set data value. Thus, after receipt of a start event on line 100, the Automatic Mode Switch Check Block 32 is activated until one of two possibilities occurs, viz. the counter reaches zero value or the set data value. Then the counter 98 as disactivated and a type of Count-Out is stored in the Count-Out Index Register 102.

The Set Data register 104 is in reality two different registers, each with its own Set Data value. One of these values is used when starting the counting in a DDD mode of operation and the other value when the counting is started in a DDI mode. Thus, when a start pulse is received the relevant value of these two values is loaded into the counter 98.

The AND-gate 106 with one of its inputs inverted prevents through the Load New Data line 108 loading of new Set Data after receipt of a start pulse.

The counter 98 is controlled by each detected ventricular event, i.e. a ventricular stimulation or an R-wave detection, supplied through the AND-gate 108. The counter 98 is controlled to count down if there is an indication that the measured interval in question in the Cardiac Event Interval Counter, see figure 9, is longer than the Atrial Tachy Limit. The counter 98 is controlled to count up if there is an indication that the measured interval between atrial signal detections is shorter than the Atrial Tachy Limit ATI. If none of these conditions is fulfilled the counting is dismissed and the counter 98 disabled through the control line Clock Enable 112 to the AND-gate 108.

If the counter 98 reaches the same value as the set value and this occurs during counting up, a signal Return Stop is delivered by the counter 98 on its output 114. This signal Return Stop stops the activities in the Automatic Mode Switch Check Block and sets the Count-Out Index 102 to Count Out. This Count-Out Index 102 is controlling other parts of the pacemaker electronics to control the mode of operation. Thus, a Count-Out indication results in operation in the non-tracking mode (DDI) and an opposite indication or reversed Count-Out indication results in operation in the normal tracking mode (DDD).

Figure 11 shows the Up/Down Counter 98 more in detail. The counter consists of a number of binary stages 116, 118 ... 120, which is enough to be able to count the maximum desired value, plus one extra binary stage 122.

When the automatic mode switch procedure is started from the normal tracking mode (DDD), as indicated by an opposite or reversed Count-Out Index value, cf. the description of figure 10 above, a loading procedure is performed. Each binary stage 116, 118, ..., 120 is then loaded with one bit, "zero" or "one", from the Set Data register, 104 in figure 10. This loading is gated to be performed when a pulse is received on the Load Control of Set Data line 124. The extra binary stage 122 will then be loaded with the binary value "zero". When the counter has counted down to "zero" on all stages 116, 118 ..., 120, all stages 116, 118, ..., 120 will be switched to "one" in response to the next pulse. The signal from the last stage 122 is controlling the Count-Out indication and the deactivation of the counting.

When the Automatic Mode Switch Check Block 32 in figure 10 is starting from the non-tracking mode (DDI), indicated by the Count-Out Index, no loading of the binary stages is performed since all bits are already set to "one". However, for the binary comparison in units 126, 128, 130, another value is used, which is equal to the number of ventricular intervals

required for change from the DDI mode to the DDD mode. The selection of a suitable value for this binary comparison is performed in gates not shown in the figure. In the units 126, 128, 130 a binary comparison is performed and when the counter value reaches the set value a Return Stop signal is delivered on the output 132. After start the counter is counting up or down depending on the logic state on the Up/Down Control of Counting line 134. The direction of the counting can be reversed after start of the counting.

Above a specific technique is described using counters and decoding logics for counting a specific number of pulses. However, the essential function of the invention consists in counting a number of ventricular intervals during a check of tachycardia indications for deciding of mode switch, and the same or similar functions can also be realised by using other techniques, e.g. microprocessor techniques.

To sum up, in the pacemaker according to the invention a mode switch from a tracking mode of operation, e.g. DDD, to a non-tracking mode, e.g. DDI, is performed when there is an atrial tachycardia with a rate exceeding a programmed limit. The determination and confirmation that a state of atrial tachycardia actually prevails are performed by using a predetermined number of stimulation intervals during which other, or preferably all, cardiac signal intervals are analysed. This phase after detection of an atrial tachycardia in DDD mode or detection of a disappeared tachycardia in DDI mode is called consideration or check phase, during which it is considered or checked if the mode should be switched or not.

Atrial events are continuously monitored by an atrial tachycardia signal detector or P-wave detector and when the interval between two consecutive atrial signals is less than a programmed atrial tachycardia limit value an index memory is set to tachy indication. When there is a measured interval between any cardiac event during a subsequent cardiac cycle,

which is longer than the programmed tachycardia limit value, the index memory is set to a non-tachy indication. The interval measurements are accomplished by two interval counters, viz. an Atrial Tachy Counter and a Cardiac Event Interval Counter. The measured values are compared to the programmed tachycardia limit value and the result of the comparison is stored in ON/OFF memories. The index information is used at the next ventricular stimulation to increase the safety in the determination of whether a state of tachycardia prevails or not, before the final decision of pacemaker mode of operation is made. Thus, at each ventricular stimulation the previous indication in the index memory is used to count up or count down the mode change counter. If there have been at least one indication during the interval between two consecutive ventricular stimulations, the mode change counter is counted up by one if the last indication is a tachy, and, if the last indication is non-tachy, the counter is counted down by one. If there is no new indication during the interval between two consecutive ventricular stimulations the mode change counter is not altered. When the counted value reaches a programmed limit a mode switch occurs on the next ventricular stimulation.

A spontaneous ventricular beat, R-wave, is controlling the mode change counter in the same way as a ventricular stimulation.

After a mode change to a non-tracking or non-synchronous mode, for example DDI or VVI, the ventricle is stimulated with a basic rate during the state of atrial tachycardia. This basic rate can be constant, for instance with a somewhat higher value than the basic rate used in the tracking DDD-mode of operation. The basic rate can, however, also be varied under the control of one or more activity or physiological sensors.

Thus, the pacemaker according to the invention operates as follows.

The atrial signals are continuously monitored, also after a mode change. As long as the indication in the index memory then shows an ongoing tachycardia the non-tracking or non-synchronous mode of operation is maintained. If a non-tachy indication appears the mode change counter will count correspondingly on the issue of the next ventricular stimulation or R-wave detection. After the mode change counter has counted down to the programmed limit number, the mode of operation is changed back to DDD.

At detection of a tachycardia the number of high rate synchronized stimulation intervals is limited to a programmed number, e.g. 3 and thereafter the mode will change to a non-synchronized mode like DDI. The similar principle is used for changing back to the synchronous DDD mode after disappearance of the atrial tachycardia. The number of stimulation intervals at the base rate without a tachycardia is programmable.

The atrial tachycardia limit value is stored in the pacemaker. This limit value can suitably be a value in the range 400 ms - 240 ms, corresponding to 150-250 beats per minute. Every measured atrial interval shorter than the atrial tachycardia limit ATI and longer than a value of e.g. 140 ms is then indicated as a tachy interval. The atrial tachycardia rate can suitably be varied in steps of 10 beats per minute.

For the detectors a Combipolar configuration can be used, as indicated above, or the normal bipolar configuration. The Combipolar technique is described in e.g. Herzschrittmacher 17:2, 1997, p.108 and EP-A1-0 596 319. As the Combipolar lead configuration gives AV-differential signals, it is important that the logic conclusions are appropriately designed to avoid that ventricular signals are falsely interpreted as atrial signals.

A situation in which the measured interval between two atrial signals is longer than the atrial tachy limit and no other interval is longer than the atrial tachy limit, this could

indicate that there is a covered atrial signal during the ventricular blanking period. For the atrial tachycardia signal detection no refractory period is used, only a technical blanking period to avoid crosstalk sensing in Combipolar mode of sensing at a ventricular stimulation or at the appearance of an R-wave.In some tachycardia situations stable covering of atrial tachycardia signals may thus occur by the blanking interval following the ventricular stimulation. The basic principles for uncovering consists then in a change during one or more stimulation intervals of the time for the ventricular stimulation. This change of time can be obtained by temporary changes of one of the pacemaker parameters resulting in a shortening or a prolonging of the PV-intervals. A suitable uncovering method for this purposes is described in US-5,683,428.

As mentioned above two types of atrial signals should be detected, viz. normal P-waves and atrial signals at atrial tachycardia. Normal P-waves for controlling the pacemaker stimulation rhythm have a stable amplitude with a variation normally less than ±15%. A too high detector sensitivity can give rise to interference detections, which is not acceptable since such false detections will influence the rhythm of the normal pacemaker operation. In case of an atrial tachycardia or an incipient atrial tachycardia the amplitude of the atrial signals normally decreases, although they sometimes increase. Atrial fibrillation signals have, however, low and varying amplitudes and also a bad slew rate compared to normal P-waves and therefore a higher atrial detection sensitivity is needed for detection of these signals.

The preferred way of detecting the atrial signals is there-fore to use one atrial signal detector for normal P-waves and one detector adapted for detecting atrial signals of lower amplitudes. The ratio between the sensitivities of the detector for detecting atrial signals in case of an incipient tachycardia and the sensitivity of the normal P-wave detector can preferably be changed in steps of 0.4 in the range 1.2-

2.0. For these two detectors two separate amplifier and filter paths adapted to the signals in question, are provided in the pacemaker electronics. The filters must be designed for adequate R-wave attenuation and T-wave attenuation. Also myocardial signals have to be attenuated and the filters must be designed to avoid ringing on the signals.

Instead of two separate detectors it is, however, also possible to use the ordinary P-wave detector, and then with two separate tachy sensitivity settings, one sensitivity suitable for the atrial signal detection at atrial tachycardia and one suitable for ordinary P-wave detection.

The above described embodiments of the pacemaker according to the invention are dual chamber pacers. However, the invention can be applied to left ventricle pacing or four chamber pacers as well.